

Summary and Conclusions of the SBU Report:

Tympanostomy tube insertion for otitis media in children

A Systematic Review

September 2008

Project Group:

Sten Hellström (Chair)

Susanna Axelsson
(Assistant Project Director)

Kristina Bengtsson Boström

Ingemar Eckerlund

Anita Groth

Kickan Håkanson

(Project Assistant)

Finn Jörgensen

Jonas Lindblom

Agneta Pettersson
(Project Director)

Marie Ryding

Inger Uhlén

Scientific Reviewers:

Ingrid Augustsson

Claes Hemlin

Ulf Persson

Christer Petersson

Karin Stenfeldt

English Translation:

Ken Schubert

Report: Tympanostomy tube insertion for otitis media in children

Type: Systematic Review • ISBN: 978-91-85413-22-5 • ISSN: 1400-1403

Report no: 189 • Publishing year: 2008

SBU's Conclusions

This SBU report reviews the scientific evidence for tympanostomy tube insertion in the tympanic membrane (eardrum) of children with recurrent acute otitis media (inflammation of the middle ear) or long-term episodes of secretory otitis media (with fluid accumulation in the middle ear). Although these conditions eventually heal, approximately 10 000 Swedish children a year have such severe problems due to episodes of pain, reduced quality of life or hearing loss that tympanostomy tube insertion is considered to be warranted. Annual socioeconomic costs associated with the conditions total approximately SEK 600 million.

The systematic literature review, along with a survey of clinical practice, generated the following conclusions.

- ❑ The scientific evidence for tympanostomy tube insertion in children with recurrent acute otitis media is insufficient. Given that more than 2 000 Swedish children a year receive the treatment for this indication, reliable studies are needed as soon as possible.
- ❑ Tympanostomy tube insertion for long-term secretory otitis media improves hearing (Evidence Grade 1) and quality of life (Evidence Grade 2) for at least 9 months. Treating children with this indication in such a manner is justified if they have objectively verified hearing loss and accompanying reduction in quality of life. Forms that have been tested for children with diseases of the ear can be used to assess quality of life.

- ❑ Adenoidectomy improves hearing at 6-month follow-up as effectively as tympanostomy tube insertion in children with long-term secretory otitis media (Evidence Grade 3). Combining tympanostomy tube insertion with adenoidectomy does not lead to further hearing improvement at 3-month follow-up (Evidence Grade 2).
- ❑ Suctioning out fluid in the middle ear in combination with tympanostomy tube insertion does not extend functionality or reduce obstruction of the tube. Routine removal of tubes that are not spontaneously discharged has not been shown to reduce the risk of complications.
- ❑ Bathing and swimming do not increase the risk of tympanostomy tube otorrhoea (discharge) (Evidence Grade 3). Preventive measures such as earplugs or eardrops when bathing or swimming have little or no effect (Evidence Grade 2).
- ❑ The scientific evidence is insufficient to determine whether tympanostomy tube insertion is cost-effective for recurrent acute otitis media or secretory otitis media.



SBU's Summary

Background

Approximately 15 000 Swedish children are diagnosed each year with recurrent acute otitis media, while 400 000 have episodes of secretory otitis media, often with hearing loss. According to current Swedish guidelines, tympanostomy tube insertion¹ is indicated for children who have had at least three episodes of acute otitis media within 6 months and those who have had secretory otitis media for at least 3 months. An estimated 10 000 children a year receive tympanostomy tube insertion. According to the National Register for Ear, Nose and Throat Care, 75% of tympanostomy tube insertion procedures are performed on children with long-term secretory otitis media, 21% on children with recurrent acute otitis media and 4% on children with other indications.

SBU identified a need to assess the benefits and cost-effectiveness of tympanostomy tube insertion.

The task of the project group was to review the literature with regard to the following questions.

- For what indications is tympanostomy tube insertion effective in the long and short run?
- Is tympanostomy tube insertion more effective than other options?

¹ Treatment of acute ear inflammation in children: consensus statement, 10–12 May 2000 conference. Federation of Swedish County Councils, Swedish Medical Research Council and Swedish National Board of Health and Welfare. Swedish Medical Research Council, Stockholm; 2000.

- Is tympanostomy tube insertion even more effective if an adenoidectomy is performed at the same time?
- How does tympanostomy tube insertion affect quality of life?
- Are there any technical aspects of tympanostomy tube insertion that influence its effectiveness?
- How do various clinical routines following tympanostomy tube insertion influence its effectiveness?
- How common and serious are complications of tympanostomy tube insertion?
- How should tympanostomy tube otorrhoea be prevented and treated?
- Are there risk factors that influence the effectiveness of tympanostomy tube insertion?
- Is tympanostomy tube insertion cost-effective for recurrent acute otitis media or secretory otitis media?

Symptoms

Acute otitis media arrives suddenly, often along with pain and fever. The child may sleep fitfully or wake up in the middle of the night with an earache. Secretory otitis media may cause hearing loss and a feeling of fullness in the ear. Fever and pain are not normally among the complaints. But the child might be easily irritated and have difficulty concentrating.

Occurrence

Apart from non-specific upper respiratory infections, acute otitis media and secretory otitis media are the most common conditions for which doctors see children. Swedish studies show that more than half of all children have at least one episode of acute otitis media before the age of 4. Approximately 10% have recurrent acute otitis media (at least three episodes within 6 months), usually between the ages of 6 and 24 months. Such children usually have long-term episodes of secretory otitis media as well.

Most children have at least one episode of secretory otitis media before starting school. Almost two thirds heal within a month and approximately 90% within 6 months, but relapse is common. An episode that lasts at least 3 months is regarded as long-term.

Diagnosis

To confirm that fluid or pus has accumulated in the middle ear, the tympanic membrane must be inspected and its mobility assessed. The same diagnostic methods are used for acute otitis media and secretory otitis media. The goal is to identify only children with otitis media, minimising the number of false positive and false negative results. A combination of pneumatic otoscopy and tympanometry has been shown to be most accurate, followed by otomicroscopy alone.

To determine the severity of secretory otitis media, the child's hearing must also be examined.

Tympanostomy Tube Insertion

The discovery that symptoms of diseases of the middle ear are relieved if an incision is made in the tympanic membrane dates from the early 19th century. Sir Astley Cooper, a surgeon and anatomist, experimented with making an incision in the tympanic membrane but it healed quickly and the symptoms

recurred. Almost 150 years passed before a practical application emerged. A cut-off polyethylene tube placed in the incision kept it open for several weeks and allowed the symptoms to improve. Many different types of tubes have been tried through the years in an attempt to make them remain in place longer and cause as few complications as possible. There are currently two main types of tubes, which are designed to remain in place for the short (8–24 months) or long run.



Figure 1 Different types of tympanostomy tubes.

Tympanostomy Tube Insertion in Various Countries

As shown in the figure below, the percentage of children who receive tympanostomy tube insertion varies from country to country. For instance, more than three times as many Dutch and Danish children per 10 000 receive the treatment as Swedish children.

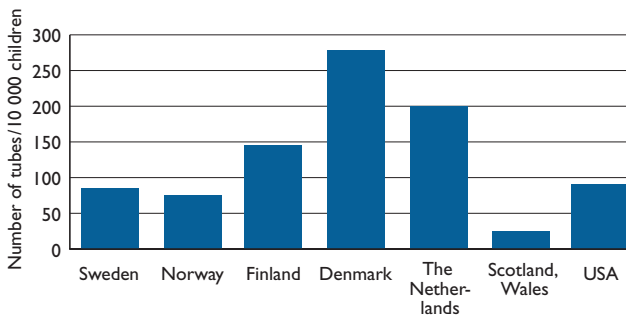


Figure 2 Tympanostomy tubes inserted in various countries per 10 000 children.

Methodology

Selection of Studies

The primary scientific evidence for addressing the project's questions was to be systematic reviews of high quality and clinical relevance, supplemented by original studies published later. When such overviews were lacking or deemed not to have high quality and clinical relevance, the original studies were examined.

To address the various questions, searches were performed in the Cochrane Library, PubMed, Embase, Central and National Health Service Economic Evaluation Database (NHSEED) for 1966 until April 2007. The studies were to include all children and adolescents, and the diagnosis of recurrent acute otitis media and long-term secretory otitis media were to be subject to the same criteria as those currently used in Sweden. The effectiveness of treatment for recurrent acute otitis media was to be measured as the number of new episodes and the impact on quality of life. The effect on hearing, language development and quality of life was assessed in the case of long-term secretory otitis media.

The health economic studies were to cover both costs and effectiveness, be relevant to Swedish conditions and contain comparisons with the best alternative to tympanostomy tube insertion.

Two reviewers examined each list of titles and abstracts from the database searches. A full text version was ordered for all articles that at least one reviewer deemed to have met the inclusion criteria. Articles that turned out not to address the project's questions were eliminated.

Fact box 1 Study Quality and Relevance, Evidence Grade.

Study quality and relevance refers to the scientific quality of a particular study and its ability to reliably address a specific question.

Evidence Grade refers to the total scientific evidence for a conclusion.

Evidence Grade 1 – Strong Scientific Evidence

A conclusion assigned Evidence Grade 1 is supported by at least two studies with high study quality and relevance among the total scientific evidence. If some studies are at variance with the conclusion, the Evidence Grade may be lower.

Evidence Grade 2 – Moderately Strong Scientific Evidence

A conclusion assigned Evidence Grade 2 is supported by at least one study with high study quality and relevance, as well as two studies with medium study quality and relevance, among the total scientific evidence. If some studies are at variance with the conclusion, the Evidence Grade may be lower.

Evidence Grade 3 – Limited Scientific Evidence

A conclusion assigned Evidence Grade 3 is supported by at least two studies with medium study quality and relevance among the total scientific evidence. If some studies are at variance with the conclusion, the Evidence Grade may be insufficient or contradictory.

Insufficient Scientific Evidence

If no studies meet the study quality and relevance criteria, the scientific evidence is rated as insufficient to draw any conclusions.

Contradictory Scientific Evidence

If different studies are characterized by equal study quality and relevance but generate conflicting results, the scientific evidence is rated as contradictory and no conclusions can be drawn.

Quality Assessment

At least two members of the project group reviewed each study that met the inclusion criteria. SBU's standard templates were used as support for the assessments. Each study was assigned high, medium or low study quality and clinical relevance.

Evidence Grading

The studies that were assigned high or medium quality and clinical relevance served as the bases for conclusions on the scientific evidence. As shown in Fact box 1, each conclusion was assigned an evidence grade between 1 (strong scientific evidence) and 3 (limited scientific evidence). In the case of questions for which studies were not available or had low quality and clinical relevance, the conclusion was that evidence was lacking.

Results of the Literature Review

For what Indications is Tympanostomy Tube Insertion Effective in the Long and Short Run?

Two studies of medium quality and clinical relevance examined the effectiveness of tympanostomy tube insertion for recurrent acute otitis media. Six-month follow-up showed that the number of episodes of acute otitis media decreased by more than half in children who received tympanostomy tube insertion as compared with those who were not treated at all. One study found that the number of episodes was still lower after a year, while the other study did not perform additional follow-up. The review also included a study of low quality. The study did not show any effect of tympanostomy tube insertion at 1-year or 2-year follow-up. Thus, the scientific evidence suggests that tympanostomy tube insertion is effective for 6 months but is insufficient to conclude that the effect has been verified.

Three studies of high or medium quality and clinical relevance examined whether hearing and language development in children with long-term secretory otitis media improved more if tympanostomy tube insertion was performed at an early stage than if there was a 9-month watchful waiting. One study found that hearing had improved more at 6-month and 12-month follow-up in children who were treated early. The second study showed that children who were treated had better hearing and language comprehension after 9 months. The effect was gone at 18-month follow-up, but 85% of children who were not treated early had also received a tube by that point. The third study reported no short-term results. The children's hearing was examined when they were 6 years old and exhibited no difference between the two groups.

An additional study, which had high quality and clinical relevance, found that hearing improved significantly when tympanostomy tube insertion was performed, as opposed to myringotomy (making an incision in the tympanic membrane). The effect remained at 2-year follow-up.

Thus, the conclusion is that hearing improves after tympanostomy tube insertion for long-term secretory otitis media as compared to no treatment at all and the effect remains for at least 9 months (Evidence Grade 1). Because the scientific evidence is contradictory, it cannot be determined whether hearing remains better over the long term or whether language development is affected.

Is Tympanostomy Tube Insertion more Effective than Pharmacological Options?

Antibiotics are an alternative to tympanostomy tube insertion for recurrent acute otitis media. Only one study, which had low quality, compared tympanostomy tube insertion to long-term prevention with antibiotics. The study showed that amoxicillin was significantly more effective. Short-term preventive antibiotic therapy has not been compared with tympanostomy tube inser-



tion. Thus, there is insufficient evidence to compare the effectiveness of antibiotics with tympanostomy tube insertion.

Other therapies that have been tried are immunoglobulin and pneumococcal vaccination, but they have not been compared with tympanostomy tube insertion. Given the few number of studies, all of which have low quality, the effectiveness of immunoglobulin cannot be compared with control treatment. One study of high quality and clinical relevance and one study of medium quality and clinical relevance examined whether pneumococcal vaccination reduces the number of new episodes in children with recurrent acute otitis media as compared with the control vaccine. The children were age 1–7 at the time of vaccination. The number of new episodes was not affected.

Is Tympanostomy Tube Insertion more Effective than Other Surgical Options? Is Tympanostomy Tube Insertion Even More Effective if an Adenoidectomy is Performed at the Same Time?

The scientific evidence for comparing the effectiveness of tympanostomy tube insertion with performing an adenoidectomy is based on five studies of medium quality and clinical relevance for recurrent acute otitis media, as well as one study of high quality and clinical relevance and three studies of medium quality and clinical relevance for long-term secretory otitis media. For recurrent acute otitis media in children younger than 2 years of age, the risk of new episodes of acute otitis media did not decrease if an adenoidectomy was performed when the tube was inserted (Evidence Grade 3). For long-term secretory otitis media, an adenoidectomy and tympanostomy tube insertion were equally effective (Evidence Grade 3). Hearing at 3-month follow-up and later did not improve further if the two procedures were combined (Evidence Grade 2).

Are there any Technical Aspects of Tympanostomy Tube Insertion that Influence its Effectiveness?

The scientific evidence included 16 studies of medium quality and clinical relevance. With few exceptions, the evidence was insufficient to assess the effect of various characteristics of the tube or of various measures during the procedure.

A single study compared two manufacturing materials: titanium and plastic. The study found no difference in the period of functionality or the risk of infection. Because available studies yielded contradictory results, the possible benefits of lining the inside of the tube with silver oxide could not be assessed.

Studies concerning the procedure itself and associated routines were usually of low quality. Whether the direction of the incision was of any importance or whether the position of the tube in the tympanic membrane affected how long the tube continued to function could not be determined. Suctioning out fluid in the middle ear did not affect the functionality of the tube (Evidence Grade 3). Possible benefits of irrigating and disinfecting the middle ear to reduce the risk of postoperative tympanostomy tube otorrhoea could not be assessed.

How do Various Clinical Routines Following Tympanostomy Tube Insertion Influence its Effectiveness?

A single study of low quality and clinical relevance examined routines to follow up on children who receive tympanostomy tube insertion for recurrent acute otitis media or long-term secretory otitis media. Thus, the question cannot be answered.

A handful of studies of low quality and clinical relevance examined whether the risk of complications decreases if tubes that do not come out spontaneously after 2–3 years are removed. No benefits were identified.

How Common and Serious are Complications of Tympanostomy Tube Insertion?

Complications refer to changes in the tympanic membrane or middle ear. The scientific evidence consists of one study of low quality and clinical relevance and ten studies of medium quality and clinical relevance.

The studies showed that the complications are rarely serious. Chronic perforations, which occasionally lead to hearing loss (conduction defects), appear in up to 5% of ears in which tympanostomy tubes have been inserted, as opposed to 1% of those with otitis media in which the procedure has not been performed (Evidence Grade 3). Long-term follow-up, in which children were examined for up to 15 years after the procedure, could not determine the extent to which the perforations heal with time.

The most common complication is myringosclerosis (formation of dense connective tissue in the tympanic membrane). The condition appears in approximately half of the ears in which tympanostomy tubes have been inserted, as well as 1–20% of those with otitis media on which the procedure has not been performed. The studies found that the tissue does not go away with time but that it has no affect on hearing (Evidence Grade 2).

How Should Tympanostomy Tube Otorrhoea be Prevented and Treated?

Tympanostomy tube otorrhoea is common. Its frequency within 14 days after the procedure varies from 5–49% in different studies.

Two studies of high quality and clinical relevance and seven studies of medium quality and clinical relevance examined whether there are any preventive measures that reduce the risk of tympanostomy tube otorrhoea. Many different antibiotics with or without steroids were compared to each other or to no treatment. All in all, the number of episodes of postoperative tympanostomy tube otorrhoea was cut in half if antibiotic wdrops were administered at the time of the procedure (Evidence Grade 2).

Tympanostomy tube otorrhoea unrelated to the procedure itself is a common (26–83%) complication and is usually associated with episodes of acute otitis media. Two studies of high quality and clinical relevance and two studies of medium quality and clinical relevance compared various treatments for tympanostomy tube otorrhoea. A single study compared the effectiveness of oral antibiotics with placebo. Thus, the scientific evidence to assess the possible benefits of oral antibiotics is insufficient. Eardrops containing ciprofloxacin (a quinolone antibiotic) and the steroid hormone dexamethasone are more effective than quinolones alone. Eardrops with quinolones are avoided in Sweden if the patient has an incision or tube in the tympanic membrane on the belief that the steroid can damage the middle ear. No published studies have examined the effect of the eardrops containing antibiotics and hydrocortisone that are used in Sweden.

To prevent tympanostomy tube otorrhoea, children are often instructed to wear earplugs or bathing caps, or avoid putting their heads under water, when swimming or bathing. One study of high quality and clinical relevance and four studies of medium quality and clinical relevance examined whether the number of episodes of tympanostomy tube otorrhoea decreases if ears are protected from water. The study of high quality and clinical relevance concluded that a child would have to wear earplugs for almost 3 years to avoid an episode of tympanostomy tube otorrhoea, while the other studies reported no results in this regard. Thus, our conclusion is that bathing and swimming do not increase the risk of tympanostomy tube otorrhoea (Evidence Grade 3). Protecting the ears when bathing or swimming reduces the number of episodes of tympanostomy tube otorrhoea either negligibly or not at all (Evidence Grade 2).

How Does Tympanostomy Tube Insertion Affect Quality of Life?

The scientific evidence consists of three studies of children with long-term secretory otitis media. No studies were found that examined quality of life in children with recurrent acute otitis media on whom tympanostomy tube insertion had been performed. Two studies, both of medium quality and clinical relevance, used the OM-6 questionnaire, which has been tested for children with ear diseases. OM-6 measures six components: physical suffering, hearing loss, speech impairment, emotional distress, activity limitations and caregiver concerns. All components improved, and the effect remained at follow-up.

A third study, which was of high quality and clinical relevance, examined whether tympanostomy tube insertion affects behaviour. At the first (9-month) follow-up, children on whom the procedure had not been performed had more problems than those on whom it had. The differences had evened out at 18-month follow-up, by which time the procedure had been performed on the remaining children.

Thus, the conclusion is that quality of life improves in children with long-term secretory otitis media after tympanostomy tube insertion has been performed. The effect remains during the follow-up period, which ranged from 6 weeks to 9 months in the different studies (Evidence Grade 2).

Are there Risk Factors That Influence the Effectiveness of Tympanostomy Tube Insertion?

Two risk factors have been examined: passive smoking and concurrent disease. Two studies concerning the effects of passive smoking were reviewed. One of them concluded that passive smoking does not have any impact on the frequency of complications. The other study showed a significantly higher frequency of premature extrusion, tympanostomy tube otorrhoea and myring-

osclerosis. Thus, whether passive smoking reduces the effectiveness of tympanostomy tube insertion cannot be determined.

Some groups of children run an increased risk of secretory otitis media. Among them are those with Down's syndrome, as well as those with lip, jaw or palate defects. Two studies of medium quality and clinical relevance examined the effectiveness of tympanostomy tube insertion in children with Down's syndrome. Fewer of them had better hearing after tympanostomy tube insertion than those who did not have Down's syndrome (Evidence Grade 3). Whether the finding is due to the higher occurrence of sensorineural hearing loss in children with Down's syndrome is unclear. One study also showed that children with Down's syndrome have a higher frequency of complications. More than 90% of children with lip, jaw or palate defects have episodes of secretory otitis media and are thereby candidates for tympanostomy tube insertion. The two studies included in the review arrived at opposite conclusions regarding the benefits of tympanostomy tube insertion. Thus, it cannot be determined whether children with lip, jaw or palate defects have more complications or other effects of the procedure than those without such defects. The control groups for both Down's syndrome and lip, jaw and palate defects consisted of children without those conditions.

Is Tympanostomy Tube Insertion Cost-Effective for Recurrent Acute Otitis Media or Secretory Otitis Media?

One study concerning recurrent acute otitis media and one study concerning long-term secretory otitis media met the inclusion criteria. Because the scientific evidence was so limited, we supplemented the review with our own health economic model analyses. The results suggest that treatment strategies that include tympanostomy tube insertion for long-term secretory otitis media may be cost-effective. But reliable conclusions require knowledge about the willingness of the community to pay for the benefits that the procedure offers. Our conclusion is that the scientific evidence is

insufficient to determine whether tympanostomy tube insertion is cost-effective for recurrent acute otitis media or long-term secretory otitis media.

Survey of Clinical Practice

There are no comprehensive statistics regarding the number of Swedish children age 16 or younger on whom tympanostomy tube insertion is performed each year. Based on sales figures from the companies that supply the tubes, the maximum is estimated to be 10 000. A mail survey was conducted to gain an overview of clinical practice among primary caregivers in the diagnosis and treatment of children with recurrent acute otitis media or secretory otitis media. The questionnaire was sent to a sampling of general practitioners, ear, nose and throat specialists and directors of ear, nose and throat clinics. The results may be summarised as follows.

- Most general practitioners reported that they used otoscopy (looking into the ear with a special instrument) to diagnose both recurrent acute otitis media and secretory otitis media. Over 70% used otoscopy with a Siegle's speculum or otomicroscopy to diagnose secretory otitis media.
- Hearing examinations were performed more often prior to than after tympanostomy tube insertion. In both cases, examining children age 4 and older was more common than examining those who were younger.
- General practitioners usually treated children who had tympanostomy tube otorrhoea with oral antibiotics, whereas ear, nose and throat specialists preferred eardrops containing antibiotics.

- In accordance with clinic guidelines, most general practitioners recommend restrictions on bathing and swimming for children on whom tympanostomy tube insertion has been performed.

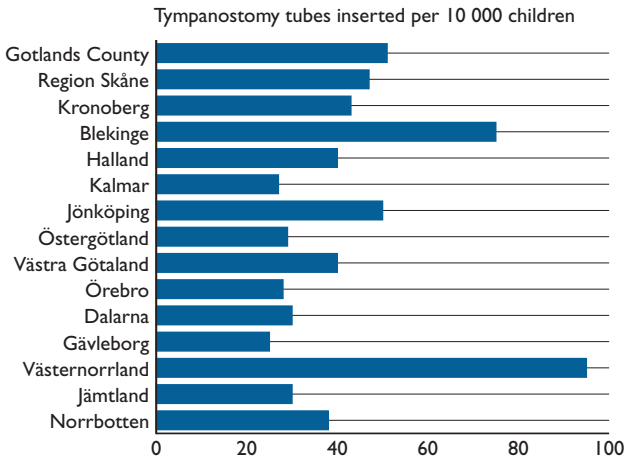


Figure 3 Tympanostomy tubes inserted per 10 000 children per year by county. Source: SBU's questionnaire for directors of ear, nose and throat clinics, 2006.

The clinical practice survey can be used to estimate the frequency of tympanostomy tube insertion in children age 18 or younger in 15 Swedish regions. In most of the regions, the figure is 30–50 per 10 000.

Conceivable Changes in Clinical Practice

Clinical practice as reflected by responses to the project's questionnaire, as well as by Sweden's quality registers, frequently conform with the evidence that is currently available. But the methods used in clinical practice appear to differ in some respects from those for which there is the most reliable scientific evidence.

Expansion of Diagnostic Methods in Primary Care to Ensure Greater Accuracy

According to the survey, most general practitioners use otoscopy alone to examine the tympanic membrane. Systematic overviews show that the method is insufficient to diagnose acute otitis media and secretory otitis media. Diagnosis is more accurate if otomicroscopy, pneumatic otoscopy and tympanometry are used. If primary caregivers obtain greater access to such methods, the frequency of false positive results for acute otitis media will probably decrease. That should lead to less use of antibiotics and fewer referrals to ear, nose and throat specialists.

Clearer Indication for Tympanostomy Tube Insertion to Treat Secretory Otitis Media

In addition to a diagnosis of long-term secretory otitis media, children who are referred to an ear, nose and throat clinic for assessment should have such pronounced hearing loss that their quality of life is affected. In children on whom it is difficult to perform hearing examinations for one reason or another, rating scales to measure quality of life may be useful. Thus, a form that rates quality of life and that has been validated for secretory otitis media in Swedish children should be developed, and caregivers concerned should be trained in how to use it.

Adoption of Hearing Examinations by Local Healthcare Programmes

Although the indication for tympanostomy tube insertion in secretory otitis media includes hearing loss, not all children are given a hearing examination prior to the procedure. Nor is a routine examination always performed after the procedure. If a hearing examination were adopted on a routine basis prior to tympanostomy tube insertion, the procedure would not be performed on certain children with minor hearing loss, while it would be accelerated in children with major hearing loss and reduced quality of life.

Phasing Out of Certain Routine Measures

There is no scientific evidence for suctioning out fluid in the middle ear during tympanostomy tube insertion or for routine removal of tubes that do not come out spontaneously within 2–3 years.

Discontinuation of Oral Antibiotics to Treat Tympanostomy Tube Otorrhoea

Tympanostomy tube otorrhoea is frequently treated with oral antibiotics despite insufficient scientific evidence that they are effective.

Allowing Children on whom Tympanostomy Tube Insertion has been Performed to Bathe and Swim without Special Restrictions

Most ear, nose and throat specialists instruct children on whom tympanostomy tube otorrhoea has been performed to be careful when bathing or swimming. Given that various restrictions, such as avoiding water or using earplugs, have little or no effectiveness, there is generally no reason to restrict bathing and swimming (with the exception of nose diving, for which there have been no studies).

Research Needs

Although tympanostomy tube insertion has been used for almost 50 years, basic questions about its effectiveness remain unanswered. Many studies are old and have low quality and clinical relevance, partly because the definitions of recurrent acute otitis media and secretory otitis media have changed with time. Considering that more than 2 000 Swedish children with recurrent acute otitis media receive tympanostomy tube insertion every year while the scientific evidence is insufficient, additional randomised trials are urgent.

Other studies that are needed to assess the appropriate scope of tympanostomy tube insertion are as follows:

- Randomised trials that confirm the effectiveness of tympanostomy tube insertion on quality of life in Swedish children with long-term secretory otitis media.
- Randomised trials concerning the effectiveness of eardrops for tympanostomy tube otorrhoea.
- Randomised trials concerning the effectiveness of tympanostomy tube insertion compared to hearing aids in children with Down's syndrome or lip, jaw or palate defects.



Reports *published by SBU*

SBU Reports in English

Dementia (2008), three volumes, no 172E/1+2+3
Obstructive Sleep Apnoea Syndrome (2007), no 184E
Interventions to Prevent Obesity (2005), no 173E
Moderately Elevated Blood Pressure (2004), Volume 2, no 172/2
Sickness Absence – Causes, Consequences, and Physicians' Sickness Certification Practice, Scandinavian Journal of Public Health, suppl 63 (2004), 167/suppl
Radiotherapy for Cancer (2003), Volume 2, no 162/2
Treating and Preventing Obesity (2003), no 160E
Treating Alcohol and Drug Abuse (2003), no 156E
Evidence Based Nursing: Caring for Persons with Schizophrenia (1999/2001), no 4E
Chemotherapy for Cancer (2001), Volume 2, no 155/2
CABG/PTCA or Medical Therapy in Anginal Pain (1998), no 141E
Bone Density Measurement, Journal of Internal Medicine, Volume 241 Suppl 739 (1997), no 127/suppl
Critical Issues in Radiotherapy (1996), no 130E
Radiotherapy for Cancer, Volume 1, Acta Oncologica, Suppl 6 (1996), no 129/1/suppl
Radiotherapy for Cancer, Volume 2, Acta Oncologica, Suppl 7 (1996), no 129/2/suppl
Mass Screening for Prostate Cancer, International Journal of Cancer, Suppl 9 (1996), no 126/suppl
Hysterectomy – Ratings of Appropriateness... (1995), no 125E
Moderately Elevated Blood Pressure, Journal of Internal Medicine, Volume 238 Suppl 737 (1995), no 121/suppl
CABG and PTCA. A Literature Review and Ratings... (1994), no 120E
Literature Searching and Evidence Interpretation (1993), no 119E
Stroke (1992), no 116E
The Role of PTCA (1992), no 115E
The Problem of Back Pain – Conference Report (1989), no 107E
Preoperative Routines (1989), no 101E

SBU Summaries in English (1999–2008)

Tympanostomy Tube Insertation for Otitis Media in Children (2008), no 510-40
Caries – Diagnosis, Risk Assessment and Non-Invasive Treatment (2008), no 510-39
Methods of Early Prenatal Diagnosis (2007), no 510-38
Light Therapy for Depression and Other Treatment of Seasonal Affective Disorder (2007), no 510-37

Dyspepsia and Gastro-oesophageal Reflux (2007), no 510-36
Obstructive Sleep Apnoea Syndrome (2007), no 510-35
Benefits and Risks of Fortifying Flour with Folic Acid to Reduce the Risk of Neural Tube Defects (2007), no 510-34
Methods of Promoting Physical Activity (2007), no 510-33
Mild Head Injury – In-hospital Observation or Computed Tomography? (2007), no 510-32
Methods of Treating Chronic Pain (2006), no 510-31
Malocclusions and Orthodontic Treatment in a Health Perspective (2005), no 510-30
Psychiatric Risk Assessment Methods – Are Violent Acts Predictable? (2005), no 510-29
Treatment of Anxiety Disorders (2005), no 510-28
Interventions to Prevent Obesity (2005), no 510-27
Chronic Periodontitis – Prevention, Diagnosis and Treatment (2004), no 510-26
Moderately Elevated Blood Pressure (2004), no 510-25
Treatment of Depression (2004), no 510-24
Prescribed Sick Leave – Causes, Consequences, and Practices (2004), no 510-23
Osteoporosis – Prevention, Diagnosis and Treatment (2003), no 510-22
Radiotherapy for Cancer (2003), no 510-21
Hearing Aids for Adults (2003), no 510-20
Prevention of Dental Caries (2002), no 510-19
Prevention, Diagnosis & Treatment of Venous Thromboembolism (2002), no 510-18
Obesity – Problems and Interventions (2002), no 510-17
Hormone Replacement Therapy (2002), no 510-16
Treatment of Alcohol and Drug Abuse (2001), no 510-15
Chemotherapy for Cancer (2001), no 510-14
Treatment of Asthma and COPD (2000), no 510-13
Dyspepsia – Methods of Diagnosis and Treatment (2000), no 510-12
Back Pain, Neck Pain (2000), no 510-11
Urinary Incontinence (2000), no 510-9
The Patient–Doctor Relationship (2000), no 510-8
Prognostic Methods for Acute Coronary Artery Disease (1999), no 510-10

SBU Alert Reports

Early assessment of new health technologies. Find them at www.sbu.se/alert in PDF format.

To order SBU Reports?

There are also several reports in Swedish. All reports can be ordered at www.sbu.se, by e-mail (info@sbu.se), by phone (+46-8-412 32 00) or by fax (+46-8-411 32 60).

